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May 16, 2025

BY CM/ECF & FED EX
The Honorable Mitchell S. Goldberg
U.S. District Court for the
Eastern District of Pennsylvania
James A. Byrne U.S. Courthouse, Room 17614
601 Market Street
Philadelphia, PA 19106-1797

Re: *Arbutus Biopharma Corporation, et. al. v. Moderna, Inc., et. al.* C.A. No. 22-252-MSG

Dear Chief Judge Goldberg:

Plaintiffs write to request reconsideration of one portion of Your Honor's May 16, 2025 Order. D.I. 468. Plaintiffs respect Your Honor's authority to manage the case and agree there is a need for case narrowing here, and thus normally would not seek reconsideration. However, the patent-narrowing aspect of the Court's Order would so singularly prejudice Plaintiffs as to necessitate raising the issue with Your Honor.

Plaintiffs are severely prejudiced by the timing and procedure in the Court's Order to narrow significantly the number of asserted ***patents*** before knowing how summary judgment and *Daubert* motions will be resolved, and without any opportunity to amend an asserted patent that is implicated by resolution of the parties' motions. Moreover, the post-summary judgment patent limit does not account for the unique liability and damages issues implicated by the asserted patents, including significant differences in the issuance and expiry dates of the Patents-in-Suit—an issue not present in the case Moderna cited to justify its request to narrow the number of asserted patents at this stage of the case.[1]

There are unique and important issues related to liability and damages for various of the Patents-in-Suit. The number of asserted patents would not materially affect the presentation of evidence to the jury but do affect Plaintiffs' ability to obtain relief for Moderna's infringement. In particular, regardless of which Lipid Composition claims are at issue, Plaintiffs intend to advance three main theories of infringement at trial: (a) literal infringement based on the aggregate lipid composition of the Accused Product, (b) literal infringement based on the fractionation testing performed by Dr. Schuster, and (c) infringement under the doctrine of equivalents. Moderna contests each of these theories. Thus, while the infringement evidence is

[1] Moderna's original proposal for case narrowing, *see* D.I. 457, did not propose any patent narrowing. Despite repeated requests from Plaintiffs for Moderna to share its revised proposal following the May 7 hearing, Moderna finally provided that proposal—in which it first raised the prospect of patent narrowing—only one business day before the parties' submissions were due on May 13. *See* D.I. 466, Ex. A.

largely the same across the Lipid Composition Patents, the potential effect on damages and liability varies greatly for several reasons:

1. **Date of Patent Issuance and Expiry**. The vast majority of Moderna's infringing sales of its COVID-19 vaccine are concentrated in the first few years following its release. During this period, one of the Patents-in-Suit expired (the '651) and a second issued (the '378). Forcing Plaintiffs to choose between these patents may therefore substantially affect the scope of Moderna's infringement liability and damages depending on the jury's findings.
2. **Estoppel and Issue Preclusion**. The '069, '435, and other Lipid Composition Patents potentially are differently situated with respect to IPR estoppel and issue preclusion. Both parties agree that IPR estoppel applies to the '069 patent. The parties dispute (1) whether IPR estoppel applies to the '435 patent, and (2) whether issue preclusion attaches to the Lipid Composition Patents. *See* D.I. 466 at 1; D.I. 456 at 1. Plaintiffs intend to move for summary judgment on these issues. The disposition of the motions may impact the value of those patents and thus the selection of patents for trial.
3. **Differing Effect of Infringement Theories on Different Patents.** The jury's determination of infringement under the three theories Plaintiffs intend to advance could potentially lead to vastly different infringement and damages outcomes for each of the Lipid Composition Patents. Thus, while the evidence presented at trial will be largely the same irrespective of the number of patents asserted, forcing Plaintiffs to drop patents (as opposed to claims) blindly could lead to significant prejudice.

Plaintiffs acknowledge that the Court has broad discretion in administering this case. *See In re Katz*, 639 F.3d 1303, 1313 (Fed. Cir. 2011). But the Federal Circuit has been clear that plaintiffs must be given an opportunity to assert claims presenting unique liability or damages issues. *Id.* at 1312-13 ("[Plaintiff] could have sought to demonstrate that some of its unselected claims presented unique issues as to liability or damages. If, notwithstanding such a showing, the district court had refused to permit [Plaintiff] to add those specified claims, that decision would be subject to review and reversal."). Here, the theories of liability and damages differ between the Lipid Composition Patents.

To be clear, Plaintiffs agree and accept that the claims and defenses in this case should be narrowed and diligently made good-faith efforts to negotiate a fair proposal with Moderna at multiple junctures of the case. Plaintiffs accept the need to narrow the number of asserted patents prior to trial, but to do so before summary judgment and *Daubert* motions are decided gives Moderna an unfair advantage and deprives Plaintiffs of their due process rights. *See Katz*, 639 F.3d at 1313. By way of example, under the Court's Order (D.I. 468), Plaintiffs may have to drop the only patent to which Moderna currently agrees IPR estoppel applies (the '069 Patent) before knowing whether preclusion or estoppel apply to the other patents. Other potential summary judgment and *Daubert* motions similarly may impact the strength of individual claims across the Lipid Composition Patent family. Thus, forcing Plaintiffs to drop patents (as opposed to claims) before summary judgement and *Daubert* prejudicially forces Plaintiffs into a blind guessing game of Russian Roulette with their property rights.

In contrast, Moderna's defenses across the Lipid Composition Patents are nearly identical, such that modestly changing the number of Asserted Patents (while keeping the Court-ordered number of asserted claims) would not materially affect the burden on the Court. For example, Moderna is asserting most §112 defenses across numerous Lipid Composition Patents, and many are directed to "all Asserted Claims." *See, e.g.*, D.I. 456 (Ex. A at ¶¶ 22-24). As another example, ***all*** of the '435 patent's obviousness combinations are also directed to claims from other patents. *See* Ex. A at 1 (Email from Moderna confirming the paragraphs containing their obviousness combinations). The reason for this is that, although the differences across the Lipid Composition Patents implicate important differences in liability and damages, the claims of those patents—which share a common specification—share many similarities. *See* Ex. B (excerpted claims of the Lipid Composition Patents).

In the *10x Genomics* case cited in the parties' letters, D.I. 456; D.I. 466; D.I. 467, Chief Judge Connolly did not limit the number of patents until ***after*** deciding summary judgment. Plaintiffs likewise maintain that no patent narrowing should take place in advance of summary judgment and *Daubert* motions. However, at a minimum, Plaintiffs request permission to assert up to five (5) patents through summary judgment, maintaining the limit of fifteen (15) total claims.

While patent narrowing may be appropriate before trial, the Court's Order limiting the number of trial patents to no more two (2) is also highly prejudicial to Plaintiffs. While Plaintiffs accept narrowing to no more than six (6) asserted claims, the unique liability and damages issues described above readily distinguish the present case from *10x Genomics*, where the plaintiffs' asserted patents all issued within a year of each other. At a minimum, Plaintiffs thus respectfully request—and, under controlling Federal Circuit precedent, should be permitted—at least four (4) patents at trial to be decided upon resolution of the parties' summary judgment motions.[2]

If the Court is not amenable to Plaintiffs' proposal, Plaintiffs ask that Your Honor hold the Court's most recent Order (D.I. 468) in abeyance pending the upcoming conference on May 27, 2025, which Plaintiffs respectfully request be held in-person. Plaintiffs are also available should the Court wish to discuss the foregoing issues in advance of that hearing.

Respectfully submitted,

/s/ Nathan R. Hoeschen

Nathan R. Hoeschen (No. 6232)

cc: Clerk of the Court (via CM/ECF & FedEx)
All Counsel of Record (via CM/ECF & Email)

[2] Plaintiffs also look forward to the opportunity to discuss the case schedule with Your Honor at the upcoming hearing, as moving forward as expeditiously as possible remains of critical importance to Plaintiffs.